



soft tissue graft against the bone tunnel wall. In the short term, interference screw fixation needs to be strong enough to firmly hold the soft tissue graft in place and prevent pull-out or substantial loosening of the graft before the graft and bone have had a chance to heal and grow together. In the long run, it is advantageous for the soft tissue graft to fuse together with the bone tissue to form a permanent living tissue graft. Once substantial fusion of the soft tissue graft and bone tissue have occurred the interference screw becomes largely superfluous.

3. One of the challenges of interference fixation is providing an interference screw that is able to exert sufficient force to provide strong initial fixation of the soft tissue graft, but not so much force that it causes long-term damage to, and potential weakening of, the soft tissue graft. The amount of force that is applied by an interference screw against a soft tissue graft is related to the diameter of the screw relative to the diameters of the bone tunnel and soft tissue graft, as well as the relative hardness of the bone. Because of variability in bone hardness among patients, as well as variability in the thickness of soft tissue strands between different persons, designing an interference screw that is able to strike the correct balance between providing strong initial fixation, on the one hand, and preventing undo damage to the soft tissue graft, on the other, is a specific challenge of interference screw design.

4. One proposed solution is to provide a pair of interference screws that are placed at each end of the bone tunnel in order to provide bicortical fixation, *i.e.*, U.S. Patent No. 6,387,129 to Rieser et al. According to this method, an initial fixation force is applied by each interference screw in the hard cortical bone region at either end of the bone tunnel. One disadvantage of this fixation system is the practical difficulty in placing the fixation screw at the back of the bone tunnel after first drawing the soft tissue graft through the bone tunnel (*i.e.*, the screw closest the joint must be placed deeply enough to firmly engage cortical bone but not so deeply as to extend

beyond the bone tunnel and scrape against the cartilage of the joint or interfere with the passive motion of the joint).

5. The interference screw and method of the Subject Application are capable of striking the correct balance between strong initial fixation of the soft tissue graft while preventing undo damage to the soft tissue graft. The inventive interference screw provides strong initial fixation of the soft tissue graft by having a length sufficient to provide both cortical and cancellous bone fixation of the soft tissue graft.

6. The interference screw claimed in the Subject Application includes a proximal threaded section that is designed to lie primarily adjacent to cortical bone within a bone tunnel during use, and a distal threaded section that is designed to lie primarily adjacent to cancellous bone within a bone tunnel during use. The distal threaded section includes a diameter that is generally smaller than the diameter of the proximal threaded section in order for the distal threaded section to apply less force per unit length compared to the proximal threaded section.

7. I have reviewed the Office Action dated May 20, 2004 issued by the U.S. Patent and Trademark Office in the Subject Application and the references cited against the claims of the Subject Application (*i.e.*, U.S. Patent No. 2,382,019 to Miller ("*Miller*"); U.S. Patent No. 6,387,129 to Rieser et al. ("*Rieser*"); U.S. Patent No. 6,368,322 to Luks et al. ("*Luks*"); and U.S. Patent No. 6,565,566 to Wagner et al. ("*Wagner*").

8. The primary reference cited against apparatus claims 1-18, 20-21, 23-24, 28-29, 31 and 32 under 35 U.S.C. § 103(a) is *Miller*, which discloses a compound screw designed for being hammered into wood. *Miller* teaches nothing about orthopedic surgery, let alone how to design an interference screw that would be suitable for use in fixing a soft tissue graft within a bone tunnel. Based on the apparent dimensions and features of the compound screw of *Miller*

shown in the drawings, it is my opinion that the compound screw of *Miller* would be not be suitable for use in orthopedic surgery as an interference screw in securing a soft tissue graft within a bone tunnel absent significant modification.

9. Because *Miller* admittedly fails to teach or suggest every limitation contained in the apparatus claims (*i.e.*, none of the claims were rejected as being anticipated by *Miller*), the Office Action combined *Miller* with *Rieser*. *Rieser* is the only reference cited against apparatus claims 1-18, 20-21, 23-24, 28-29, 31 and 32 having anything do with fixation of a soft tissue graft within a bone tunnel.

10. *Rieser* discloses interference screws and methods for bicortical fixation of a soft tissue graft within a bone tunnel. *Rieser*, col. 2, lines 16-24. Thus, whereas interference screws within the scope of the claims of the Subject Application are designed so that a single interference screw can be used to secure a soft tissue graft within a bone tunnel, *Rieser* requires to use of two interference screws, a proximal screw positioned near the back of the bone tunnel nearest the joint and a distal screw positioned near the front of the bone tunnel furthest from the joint. *Rieser*, col. 5, lines 22.

11. Whereas the use of two interference screws according to *Rieser* is significantly more complicated than using a single interference screw, one would expect the use of two interference screws according to *Rieser* to provide bicortical fixation to more securely attach a soft tissue graft within a bone tunnel during ACL repair surgery compared with a single interference screw within the scope of the claims of the present application that only contacts a single cortical bone surface.

12. In fact, a comparative study conducted by a disinterested third party found that a single interference screw within the scope of the claims of the Subject Application provided

significantly greater initial fixation of a soft tissue graft than a pair of interference screws used in the manner disclosed in *Rieser* to provide bicortical fixation. The single interference was able to provide greater initial fixation of a soft tissue graft even though the combined length of the two interference screws used to provide bicortical fixation was greater than the length of the single interference screw within the scope of the claims of the Subject Application.

13. The comparative study, which was authored by H.C. Chang et al., is entitled "Biomechanical Testing of Tibialis Anterior Graft Tibial Tunnel Fixation with Bioabsorbable RetroScrews and BioScrew XtraLok in Porcine Bones" (hereinafter "Chang Study"). A copy of the Chang Study is attached hereto as Exhibit A.

14. The Chang Study was carried out by Haw Chong Chang, MBBS, FRCSEd (Orth); John Nyland, Ed.D., P.T., S.C.S., A.T.C.; Akbar Nawab, MD; Robert Borden, MEng, EIT; and David N.M. Caborn, MD under the auspices of the Division of Sports Medicine, Department of Orthopedic Surgery, of the University of Louisville, which is located in Louisville, Kentucky. Exh. A, Chang Study, p. 1. To the best of my knowledge and belief, neither I nor Linvatec Corporation ("Linvatec"), a licensee of the technology described and claimed in the Subject Application, authorized, funded or otherwise had any interest in the Chang Study.

15. The stated purpose of the study was to "evaluate[] the failure mode, maximum load at failure, displacement at failure, and stiffness differences of doubled tibialis anterior graft-tibial tunnel fixation using retrograde bioabsorbable interference screws" sold by Arthrex, Inc. ("Arthrex") (the Assignee of *Rieser*) and a "35-mm BioScrew XtraLok" interference screw sold by Linvatec "after cyclical loading". Exh. A, Chang Study, p. 1.

16. The 35-mm BioScrew XtraLok interference screw that was tested in the Chang Study falls within the scope of each of the independent apparatus claims, and also within the

scope of some or all of the dependent apparatus claims, of the Subject Application. As evidence of this, a spec. drawing of the 35-mm BioScrew XtraLok interference screw tested in the Chang Study is attached hereto as Exhibit B. As seen in the drawing at Exhibit B, the BioScrew is virtually identical to the interference screw depicted in Figure 2 of the Subject Application.

17. The "Retrograde" screws used in the Chang Study, also referred to as the "RetroScrews" (Exh. A, Chang Study, pp. 1-2), as well as how they were used in the Chang Study, appear to fall within the scope of the claims of *Rieser*. It is therefore my opinion that the Chang Study represents a direct comparison between the interference screws and the bicortical fixation method claimed in *Rieser* and the interference screw claimed in the Subject Application.

18. The hypothesis of the Chang Study (later proved to be incorrect) was that "[t]here is no difference in maximum load, displacement and stiffness at failure of doubled tibialis interior graft-intibial tunnel fixation using [the] Retrograde [interference screws of Arthrex] and [the] 35-mm BioScrew XtraLok [interference screw of Linvatec] after cyclical loading." Exh. A, Chang Study, p. 1.

19. The methods used in the Chang Study included "[t]welve specimens of porcine tibias [that] were divided into 6 matched pairs based on bone mineral densitometry. Wilcoxon tests comparisons were used to assess group differences ( $P < .05$ )."  
*Id.*

20. The results of the Chang Study were as follows: "[m]aximum load at failure after cyclic loading for the RetroScrew was  $778.7 \pm 177.5$  N, with a displacement of  $5.3 \pm 2$  mm and a stiffness modulus of  $204.3 \pm 52.9$  N/mm. Maximum load at failure after cyclic loading for the BioScrew XtraLok screw was  $1436.3 \pm 331.3$  N, with a displacement of  $5.9 \pm 2.6$  mm and a stiffness modulus of  $323.6 \pm 56.8$  N/mm."  
*Id.* at pp.1-2.

21. The Chang Study further states the following: "[f]ixation using XtraLok screws displayed greater maximum load at failure than RetroScrew fixation ( $P = .028$ ) as well as greater stiffness ( $P = 0.046$ ). Significant differences were not evident for displacement at final pullout. All constructs failed by graft pullout." *Id.* at p. 2.

22. Finally, the Chang Study concluded that "[f]ixation using a single 35-mm BioScrew XtraLok screw displayed increased maximum load at failure and stiffness compared with the 20-mm RetroScrew with 17-mm cortical backup fixation". In other words, a single 35 mm interference screw according to claims of the Subject Application "displayed increased maximum load at failure and stiffness" compared to two interference screws according to *Rieser* having a combined length of 37 mm. In my opinion, the ability of a single interference screw (as claimed in the Subject Application) to provide better initial fixation of a soft tissue graft than a pair of interference screws (as disclosed in *Reiser*) that not only provide bicortical fixation but have a greater combined length is a surprising and unexpected result that underscores and distinguishes the mechanical advantages of the claimed interference screw design.

23. In addition to the foregoing, sales for the BioScrew XtraLok interference screw have steadily increased since it was first introduced into the market in 2003, as shown by the document attached hereto as Exhibit C. According to the sales figures contained in Exhibit C, sales for the BioScrew XtraLok interference screw increased from \$88,761.98 in Quarter 3 of 2003 to \$94,824.44 in Quarter 4 of 2004, and then to \$143,254.92 in Quarter 1 of 2004.

24. To the best of my knowledge and belief, sales for the BioScrew XtraLok interference screw are significantly higher than sales for the Retrograde interference screws (RetroScrews) of Arthrex, even though *Rieser* was filed before the Subject Application. In fact, to the best of my knowledge and belief, the Retrograde interference screws (RetroScrews) of

Arthrex have had, to date, little acceptance in the market. Thus, not only has an interference screw within with scope of the claims of the Subject Application had good success in the market, its success and acceptance by orthopedic surgeons appears to be significantly greater than interference screws within the scope of the claims of *Rieser*.

25. It is my opinion that the Chang Study and the acceptance and market penetration of an interference screw within the scope of the claims of the Subject Application are objective evidence of the inventiveness of the claimed interference screws of the Subject Application over *Rieser*.

26. It is also my opinion that the surprising and unexpected result of a single interference screw within the scope of the claims of the Subject Application being able to provide significantly greater fixation compared to two interference screws that provide bicortical fixation and that have a greater combined length is objective evidence of the inventiveness of the claimed interference screws of the Subject Application, as well as of the claimed methods, relative to all of the cited references.

27. Finally, it is my opinion that the evidence of economic success is further objective evidence of the inventiveness of both the apparatus and method claims of the Subject Application.

28. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code, and that such willful, false statements may jeopardize the validity of the application or any patent issuing thereon.

DATED this 8 day of <sup>September</sup>~~August~~ 2004.



Hugh S. West, Jr., M.D.

Applicant

U.S. application Serial No. 09/977,154

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